

***"Animal Models of Human Viral Infections for Evaluation of Experimental Therapies"***

|                                  |                                                                                                                                                                             |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Request for Proposal No.:</b> | NIH-NIAID-DMID-01-03                                                                                                                                                        |
| <b>OMB #:</b>                    | 0990-0115                                                                                                                                                                   |
| <b>Issue Date:</b>               | December 30, 1999                                                                                                                                                           |
| <b>Issued By:</b>                | Paul D. McFarlane<br>Senior Contracting Officer, NIAID, NIH<br>Contract Management Branch<br>6700-B Rockledge Drive, Room 2230<br>MSC 7612<br>Bethesda, Maryland 20892-7612 |
| <b>Point of Contact:</b>         | Nancy M. Hershey, Contracting Officer                                                                                                                                       |
| <b>Purchase Authority:</b>       | Public Law 92-218 as amended                                                                                                                                                |
| <b>Small Business Set-Aside:</b> | No, SIC Code 8731                                                                                                                                                           |
| <b>Just In Time:</b>             | No                                                                                                                                                                          |
| <b>Offer Expiration Date:</b>    | Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH 2043".                  |
| <b>Proposal Due Date:</b>        | April 14, 2000, 4:00 P.M EST                                                                                                                                                |

Ladies and Gentlemen:

You are invited to submit a proposal in accordance with the requirements of this RFP-NIH-NIAID-DMID-01-03, entitled "Animal Models of Human Viral Infections for Evaluation of Experimental Therapies." The Government anticipates that one (1) cost reimbursement, completion type contract will be awarded for a period of seven (7) years as a result of this RFP.

This RFP will utilize the National Institute of Allergy and Infectious Diseases' (NIAID) Contract Review ON-Line (CRON) system. Offerors must submit their Technical and Business proposals ELECTRONICALLY. In addition to your electronic submission, Offerors must submit one unbound signed original HARDCOPY plus one additional unbound copy of both the technical and business proposals.

Documents not available in appropriate format (i.e., SOPs, other pertinent manuals, non-scannable figures or data, letters of collaboration/intent and/or other attachments) may be provided in hard copy. Offerors shall provide ten (10) paper copies of these documents. See Attachment F for further details.

NIAID'S CRON system will save Offerors the paper and postage costs which the mailing of multiple copies of a standard RFP proposal imposes on the Offeror. This approach will also allow us to conduct a technical review based on electronic availability of proposals which will save money that would otherwise be spent shipping proposals out to reviewers and for travel and per diem to bring in reviewers for the Technical Review meetings. We hope this will prove to be convenient to Offerors, technical reviewers and the Government. Adequate security for electronic transmission is provided by using a dedicated server with access restricted through passwords.

You must submit your electronic proposal (via the Internet) and the unbound signed original hardcopy plus one unbound copy (to the address listed in Attachment F), for receipt no later than Friday, **April 14, 2000, at 4 p.m. local time.**

Please note that the electronic copy of your proposal will need to be submitted in Adobe Acrobat portable document format (PDF). An official authorized to bind your organization must sign the hardcopy of your proposal.

**Be advised that this RFP has placed page limits on the narrative portion of the Technical Proposal. Pages in excess of the maximum will be deleted and will not be read or evaluated. See Attachment F for complete details on page limitations, proposal format and instructions on how to prepare and submit a proposal.**

The documents included with this electronic RFP package are as follows:

Attachments:

- A. [Introduction and Work Statement](#), dated December 30, 1999
- B. [Reporting Requirements and Deliverables](#), dated December 30, 1999
- C. [Evaluation Factors for Award](#), dated December 30, 1999
- D. [Specific RFP Instructions and Provisions](#), dated December 30, 1999
- E. [Applicable RFP References](#), dated December 30, 1999
- F. [How to Prepare and Submit an Electronic Proposal](#), dated December 30, 1999

In addition to the information provided in this document (i.e., The Streamlined RFP), there are five (5) other referenced documents in the [Streamlined RFP References](#) that must be retrieved, in whole or in part, in order to submit a proposal. The applicable portions of these referenced documents are explained in Attachment E, [Applicable RFP References](#) of this RFP.

If you are unable to download any of the applicable documents, please contact Nancy Hershey, by phone, fax or e-mail numbers/address listed below.

Your attention is further directed to the "[Proposal Intent Response Sheet](#)" contained in Attachment D of this document. Please complete this form and return it to this office via fax or e-mail on or before Wednesday, **March 1, 2000**. This will allow us to expedite preparations for the review of proposals.

**IF YOU INTEND TO SUBMIT A PROPOSAL, IT IS ESSENTIAL THAT YOU SUBMIT THE PROPOSAL INTENT FORM. IF YOU FAIL TO SUBMIT THE FORM, WE WILL NOT KNOW TO NOTIFY YOU TO RECEIVE ANY NOTIFICATION OF AMENDMENTS ISSUED TO THE RFP (HOWEVER, ALL AMENDMENTS WILL BE POSTED ON THE NIAID CONTRACTS MANAGEMENT HOME PAGE) AND YOU WILL NOT RECEIVE ADDITIONAL INSTRUCTIONS NECESSARY TO SUBMIT THE ELECTRONIC COPY OF YOUR PROPOSAL.**

If you have any additional questions or concerns regarding this RFP, or the electronic transmission of proposals, please contact Nancy Hershey on (301) 496-0193, or at the Internet email address [nh11x@nih.gov](mailto:nh11x@nih.gov) or by fax at (301) 480-5253. Collect calls will NOT be accepted.

Sincerely,

/ s /

Paul D. McFarlane  
Senior Contracting Officer  
Contract Management Branch  
National Institute of Allergy  
and Infectious Diseases, NIH

Attachments: A - F

## **ATTACHMENT A**

---

**RFP-NIH-NIAID-DMID-01-03**

**December 30, 1999**

### **Introduction and Work Statement**

## **ATTACHMENT A**

### **BACKGROUND**

Background and Acquisition History: Viral infections are responsible for a substantial amount of morbidity and mortality. Unlike most bacteria and fungi, viruses are obligate intracellular parasites; therefore, the discovery of agents which selectively inhibit viral pathogenesis without harming the host is much more difficult than discovering agents active against free-living bacteria and fungi. There are currently nineteen drugs that have received FDA approval for the treatment of a small number of non-HIV viral diseases. However, in many cases their utility is limited by difficulty of administration, substantial associated toxicity, and emergence of resistant viral mutants. Today the majority of viral diseases remain untreatable. Accordingly, the discovery and development of clinically effective and non-toxic antiviral therapeutic agents are essential for the control of viral infections.

The primary objective of the Animal Models Program is to evaluate experimental therapies for potential clinical efficacy (prophylactically and/or therapeutically) and toxicity in animal models of clinically important, emerging and rare human viral infections. In addition, the animal models are used to study disease pathogenesis and host response to infection. When appropriate, these models are also used for a limited amount of vaccine evaluation and pharmacokinetic studies. Animal models that are predictive of human response to a therapeutic intervention are important for the identification of experimental therapies with the best clinical potential. They are also crucial for evaluation of dosing regimens, combination drug therapies and delivery strategies. The Animal Models Program has made many significant contributions to the development of new therapies. This open recompetition is planned to assure the continuation of this vital resource for the development of antiviral therapies.

DMID's Animal Models Program was initiated in 1972. The initial contracts were competed and funded individually until 1985 when a comprehensive RFP was issued for the program. The last re-competition was in 1996 and four awards were made. The current contractors and their models are summarized in the following:

(1) Children's Hospital Center, Cincinnati, contract number N01-AI-65289 (PI, David Bernstein): Guinea pig cytomegalovirus (GPCMV); neonatal herpes and acute and recurrent genital herpes in guinea pigs; herpes simplex virus (HSV) reactivation in mice; HSV topical microbicide models (mice and guinea pigs).

(2) University of Alabama at Birmingham, contract number N01-AI-65290 (PI, Earl Kern):

Neonatal herpes and herpes encephalitis in mice; genital herpes (mice and guinea pigs); murine cytomegalovirus (MCMV); human cytomegalovirus (HCMV) in SCID-hu mouse ocular model; murine vaccinia and cowpox models.

(3) Utah State University, contract number N01-AI-65291 (PI, Robert Sidwell): Murine models of influenza, vaccinia, and cowpox.

(4) Baylor College of Medicine, contract number N01-AI-65292 (PI, Phil Wyde): Cotton rat models of respiratory syncytial virus, parainfluenza, and measles virus.

The Animal Models Program is an integral part of the antiviral drug discovery and development activities of the Antiviral Research Program in the Virology Branch. The investigators are members of the Collaborative Antiviral Testing Group (CATG). The CATG also includes investigators engaged in the in vitro screening for herpesviruses, respiratory viruses, and hepatitis B virus, and the investigators involved in the other two separately funded animal model projects—papillomavirus and hepadnavirus models. The CATG members meet annually to review progress and discuss strategies for future research. They interact with investigators engaged in basic antiviral drug design and with NIAID's National Cooperative Drug Discovery Groups. In addition, the Animal Models investigators interact closely with the clinical investigators supported by DMID's Collaborative Antiviral Study Group (CASG). This is essential so that the models can be most efficiently used to expedite and support clinical trials of promising therapies.

Therapeutic agents are provided by academic and industrial investigators, NIAID-supported National Cooperative Drug Discovery Groups and the in vitro screening facilities. The agents evaluated include nucleosides, nucleotides, peptides, immunomodulators and other chemical entities. Data from this Program have supported the clinical development of several antiviral agents, such as, famciclovir, sorivudine, cidofovir, PRO2000, oseltamivir (GS4104), and RWJ270201. Many other agents which showed efficacy in the models are entering preclinical toxicology studies.

Cidofovir and oseltamivir are two important compounds with which many clinical observations have been predicted in the animal models:

- Cidofovir is an acyclic nucleotide derivative with broad-spectrum activity against many DNA viruses by interfering with viral DNA synthesis. DMID-supported investigators have demonstrated that cidofovir is active against acyclovir-resistant HSV, can be delivered once a week and applied topically without systemic absorption, and is preferentially toxic to cells of the renal tubules.
- Oseltamivir is a novel influenza neuraminidase inhibitor; its design is based on the crystal structure of the enzyme. When studied in the murine animal model, it was shown to be orally bioavailable and was effective both prophylactically and therapeutically. Unlike amantadine and rimantadine, oseltamivir did not cause the drug-resistant mutant to arise readily.

The current four contracts are scheduled to expire in late 2000 and four new awards are anticipated with this recompetition. The emphasis for the future will be to continue to support animal models which: a) share significant features of pathology and natural history with the relevant human infection; b) utilize either a human virus or an animal virus with considerable homology to the human virus; and c) have been, or are expected to be, predictive for efficacy in subsequent human studies. As in the past, basic studies on model development, disease pathogenesis, and natural history will be encouraged as an adjunct to the primary focus on therapeutic evaluation. When appropriate, these models will also be utilized for vaccine evaluation and the pharmacokinetic analysis of an agent. Models for herpesviruses, orthopoxviruses, respiratory syncytial virus, and influenza viruses are a priority for NIAID, but offerors are also encouraged to propose models for other important emerging and/or rare viral infections as well.

This is an open competition and new investigators as well as new models will receive equal consideration for awards. The awards made will be selected to provide the most scientifically excellent, clinically relevant and comprehensive program possible. **Models for viral hepatitis, retrovirus, and papillomavirus infections are not eligible since they are supported separately by the NIAID.**

## INTRODUCTION

The purpose of this solicitation is to obtain animal models of human viral infections for the Government for the evaluation of experimental antiviral agents. The primary objective of the Animal Models Program is to evaluate experimental therapies for potential clinical efficacy (therapeutic and/or prophylactic) and toxicity in animals. Other studies such as model development, disease pathogenesis, and natural history will be encouraged as an adjunct to the primary focus on therapeutic evaluation. The models may also be utilized for vaccine evaluation and pharmacokinetic studies.

Models for herpesviruses, orthopoxviruses, respiratory syncytial virus, and influenza viruses are a priority for NIAID, but offerors are also encouraged to propose models for other important emerging and/or rare viral infections as well. A single Offeror may submit a proposal which includes one or more viruses and one or more models for a single virus. Each model within a single virus should be clearly marked in the Technical Proposal to facilitate the technical review of that model. Viruses of the same genus will be grouped together for evaluation. Each viral genus will be scored separately and a competitive range will be determined for each, even though it may have several models proposed. It is anticipated that one or two awards will be made for each viral genus, which may or may not include all of the proposed models. Decisions will be dependent upon the availability of funds, technical and scientific merit of each individual model, and programmatic priorities. It is desirable to the Government to have a diversity of viruses/models available.

If models from more than one viral genus are proposed, the business proposal should include a separate cost estimate for each genus as well as a cost estimate which combines all proposed viral genera.

Animal models for viral hepatitis, retrovirus, and papillomavirus infections will NOT be considered for award since these are subjects of other initiatives or are already being supported by other NIAID funding sources.

**[NOTE A TO OFFEROR: Viral taxonomy follows the systems defined in Murphy et al. (eds.) *Virus Taxonomy*. New York: Springer-Verlag/Wien; 1995.]**

## **WORK STATEMENT**

Independently, and not as an agent of the Government, the Contractor shall furnish all the services, qualified professional and technical personnel, material, equipment, and facilities not otherwise provided by the Government under the terms of this contract as needed to perform the work set forth below.

Specifically, the Contractor shall perform the following:

1. Provide one or more well-characterized virus-animal model(s) of a human viral disease for experimental use for evaluation of candidate antiviral therapies. For infection models, the infection of animals should be efficiently established. For other models, for example, mice transgenic with the human virus receptor gene or mice implanted with virus-infected human tissues, provide and use animals for evaluation of candidate therapies. For all models, the process of infection and/or disease pathogenesis should resemble the corresponding human disease as closely as possible.

**[NOTE B TO OFFEROR: The purpose of this solicitation is to obtain animal model systems to evaluate the clinical potential of experimental therapeutic agents for the treatment of human viral infectious diseases and to facilitate the entry of these agents into clinical trials. The model system(s) employed should have features similar to the corresponding infection in humans and these should be described. The pathologic and immunologic aspects of the model in association with virus infection should be discussed in detail and related to the ability to use this model to predict clinical effectiveness of experimental therapeutics. The Offeror should document any prior experience with the proposed model(s), with testing antiviral therapeutics, with pharmacologic and toxicologic studies, and with studies in immunology and pathology. If a non-infection model is proposed, the Offeror should explain in detail why the model is suitable. The virus should be either a human virus or an animal virus with considerable homology to the comparable human virus.]**

2. Perform preclinical evaluations of experimental therapeutic agents for viral infections as specified by the Project Officer. The therapeutic agents shall be evaluated for toxicity and efficacy (therapeutic and/or prophylactic). When appropriate, conduct immunologic, virologic, pathologic, and toxicologic tests to monitor the effects of the test agent on the infected animals, and conduct studies to evaluate novel strategies for drug delivery and dosing, including combination and sequential drug administration. These studies shall include appropriate uninfected and untreated controls. Unless directed otherwise, submit each proposed protocol/experiment/effort to the Project Officer for review, prioritization, and approval. Agents for evaluation will be provided by drug sponsors through the NIAID Project Officer.

**[NOTE C TO OFFEROR: Documentation of assays to monitor the effect of treatment on the disease process and virus replication should be provided. Sample protocols designed to treat the viral infection and/or intervene (monotherapy and/or combination therapy) in the disease processes caused by the proposed virus should be submitted with the proposal. A discussion of the logistical problems associated with the implementation of the protocol should be provided. A schedule showing the time required to analyze a therapeutic agent should be provided with an estimate of the total number of agents that could be examined at one time. The capability to conduct pharmacokinetic studies and/or vaccine evaluation is not a requirement but may be included. The number of therapeutic agents available for assessment will vary with the model and the nature and availability of appropriate agents. It is estimated that 4 agents will be initially evaluated for their toxicity and efficacy and 1-2 agents will be thoroughly evaluated annually. It is anticipated that the experimental therapeutic agents will include nucleosides, nucleotides, peptides, immunomodulators and novel chemical entities. Agent acquisition usually results from NIAID staff contacts with drug sponsors, Contractor contacts with drug sponsors, and from identification of in vitro activity in NIAID screening facilities. These agents may be irritating, toxic, and/or potentially carcinogenic or hazardous.]**

3. Perform further studies to characterize and refine the proposed model(s) and to develop new models. The contractor may be required to use animal models other than the one proposed if well-characterized animal models become available. New/emerging viruses and models may require development and evaluation of new assays.

**[NOTE D TO OFFEROR: These studies may include the characterization and definition of the model system in terms of the disease pathogenesis and host response. Delineation of the role of virus gene expression and replication, virus and host strain differences, and the significance of virus resistance may be included in these studies. It is anticipated that 5-10 percent of contract resources will be utilized to perform these studies annually.]**

4. Organize, maintain, and transfer information on protocols and test results, as well as provide reports of these, to the Project Officer. Prepare manuscripts for submission to peer-reviewed journals. Establish electronic message and document transfer capability with the Project Officer. The NIAID is connected to the INTERNET and uses IBM-compatible computers.
5. Abide by terms of the Confidentiality Agreement with drug sponsors signed by the NIAID. Copies will be provided to the Contractor prior to or simultaneous with the delivery of the therapeutic agents covered by the agreements. Provide specify procedures to safeguard proprietary information to maintain all confidential data and information in files accessible only to the Project Officer, Principal Investigator, and involved staff.

**[NOTE E TO OFFEROR: The DMID Director is often required to sign a letter of agreement to assure a drug sponsor that the patenting and future development of an experimental agent will not be jeopardized by contractor involvement or by premature disclosure of results. Primary data shall remain with the contractor; the information required by the Government will be obtained through the required reports. Patent rights to compounds evaluated in the screening program will remain with the drug sponsor who provided the drug for study. NIAID intends to obtain deviations to standard FAR clauses 52.227-11 (Patent Rights) and 52.227-14 (Rights in Data) which will state that potential drug sponsors shall retain all pre-existing rights to those compounds or products in which the drug sponsor has a proprietary interest. Intellectual property rights for unanticipated discoveries, i.e., for biological activities other than (1) antiviral efficacy, (2) toxicity, and (3) activity in combination with other drugs are the property of the contractor. The contractor is encouraged to cooperate with the drug sponsor to enter into an agreement regarding the disposition of these rights.]**

6. Conduct work in accordance with the Biosafety in Microbiological and Biomedical Laboratories guidelines, and NIH guidelines for animal care and use.

**[NOTE F TO OFFEROR: A copy of the applicable biosafety guidelines may be obtained from NIAID upon request. These guidelines will apply to all animal models which may apply to this RFP. The experience of the Offeror in working with potential biohazards such as viruses and animals, as well as toxic chemicals and radioisotopes should be addressed as well as relevant safety procedures. In addition, procedures for the care of experimental animals should be discussed.]**

7. Participate in the annual meeting of the Collaborative Antiviral Testing Group.

**[NOTE G TO OFFEROR: Funds to support this travel for the Principal Investigator, and a Co-Investigator if desired, should be included in the Business Proposal. For planning purposes assume that the meeting will last two full days and will be held in Bethesda, MD.]**

## WORK STATEMENT ATTACHMENT (1)

### SAMPLE LETTER OF AGREEMENT WITH DRUG SPONSOR

1. COMPANY may supply products, patented or unpatented, to the Division of Microbiology and Infectious Diseases (DMID) for the purpose of screening and testing for antiviral, immunomodulatory, antitumor and/or drug delivery activities in in vitro or in animal model systems. These products are to be used for screening and testing as agents with potential for the treatment or prevention of infectious diseases and for no other purpose.

The products will be evaluated by one or more of the DMID contract testing laboratories, or in any other testing laboratory which may from time to time be added to DMID but in any event will not be placed in any laboratory without COMPANY'S written permission.

2. In order to facilitate the records keeping and handling of confidential materials, we propose the following procedure:

a. COMPANY shall forward to the Virology Branch (VB) or Enteric and Hepatic Diseases Branch (EHDB) of the DMID or to the testing site, as directed by either the VB or the EHDB, the data sheets on the products to be evaluated, marked confidential. Data sheets are to be in duplicate for each product, giving pertinent available data as to chemical constitution, solubility, toxicity, and any precautions which need to be followed in handling, storing and shipping.

b. It is clearly understood that no data about the products or the results of the testing will be kept in files open to the public either by the DMID or the testing laboratories. Only those employees directly engaged in the operations of DMID will have access to the files of information regarding source and nature of confidential materials and results of evaluation.

c. It is furthermore understood that the contracts of the DMID with the testing laboratories will contain provisions to safeguard COMPANY's rights under this Agreement.

d. Because DMID's screening efforts will be accomplished in collaboration with Division's scientific staff and academic collaborators, as well as COMPANY's own staff, the Division will work to assure rapid ongoing communication of screening data to COMPANY, and the COMPANY will in turn use its best efforts to keep the Division up-to-date on COMPANY's own ongoing concomitant studies.

3. Although COMPANY recognizes that the interchange of information is generally desirable in the field of treatment for virus infection, it is our mutual understanding that COMPANY, in voluntarily supplying appropriately marked information deemed proprietary to COMPANY, including product and information regarding this product hereunder, is entitled to protection for any research and development work it has done and any such technical information it may furnish.

a. All rights, titles and interests in and to all Compounds and information provided to DMID under this Agreement by COMPANY will remain with COMPANY. This Agreement may not be construed as a grant of a license or any other right or interest beyond those expressly set forth. COMPANY understands contractors have the right to elect to retain title to inventions that are not disclosed by the COMPANY at the time that the compound(s) is submitted to DMID and made under NIAID-supported contracts [37 CFR 401.14(b)]. COMPANY reserves the right to reach an agreement with these contractors concerning the disposition of these intellectual property rights.

(1) In order that COMPANY may submit to DMID products in which COMPANY has a proprietary interest and on which COMPANY does not as yet have adequate patent protection, COMPANY may, in rare instances and with DMID's approval, submit a product under our code number only. COMPANY agrees, in this event, to reveal to DMID, under confidentiality, the structures or identities of those coded products, marked confidential, which subsequently turn out to be positive in any one of your test systems, as decided by whatever standards DMID has in existence at that time.

b. The Division agrees that the publication of biological data on products supplied by COMPANY is worthwhile and shall be encouraged. Specifically:

(1) With regard to evaluations, results on compounds in which COMPANY has a proprietary interest, COMPANY agrees that DMID and/or NIAID's Contractor(s) may publish or otherwise publicly disclose such results after a period of 6 months from the date of reporting of evaluation results to COMPANY in order for patent application to be filed. Publication of data within the 6-month period requires COMPANY'S prior consent which shall

not be unreasonably withheld.

(2) In no case will DMID publish information identifying COMPANY as the source of the compound(s) without COMPANY's prior written approval.

c. As soon as evaluations are completed and reported to the VB or EHDB of DMID, COMPANY will receive from Division a full report of the evaluation. The VB or EHDB of DMID shall be consulted whenever COMPANY desires to include DMID evaluation data in a publication or public disclosure, and appropriate credit shall be given to the U.S. Public Health Service and the DMID contract laboratory that performed the evaluation(s).

4. It is understood that the COMPANY has no control over DMID's use of the products submitted hereunder and shall not be liable for any damages which may result from DMID's use or evaluation of such products.

5. The DMID is confident that this agreement will establish the basis for mutually satisfactory cooperation. If you agree to the above, we would appreciate your countersigning below, as well as, the attached duplicate of this agreement and returning it to the DMID for our files.

Sincerely,

Carole Heilman, Ph.D.

Director, Division of Microbiology &

Infectious Diseases

NIAID, NIH

## **WORK STATEMENT ATTACHMENT (2)**

### **PROTECTION OF PROPRIETARY DATA**

Certain data and information provided to the Contractor regarding biological materials shall require confidential treatment. Information that is identified as product information and/or data which may originate from Confidentiality Agreements between any third party material provider and the government is considered confidential, and as such this information/data is to be treated confidentially. In addition, this contract will include an Advanced Understanding stating:

- (a) The contractor agrees that the use of materials provided to the contractor by or through the government for studies performed under this project shall be restricted to contract-related projects and shall not be used for any other project by the contractor or released to any other party without approval of the Contracting Officer and Project Officer.
- (b) Because the contractor will be utilizing and evaluating materials provided to the government by third parties, it is essential to protect the rights of these third parties. Therefore the contractor agrees that manuscripts/abstracts based on data/information generated under this contract will not be submitted for publication until written Project Officer clearance has been received. Contract support shall be acknowledged in all such publications. (A “publication” is defined as an issue of printed material offered for distribution or any communication or oral presentation of information.)

The Project Officer will review all manuscripts/documents in a period of time not to exceed 90 calendar days from receipt, and will either concur in the publication/disclosure, recommend changes, or as applicable, refer the document to the third party supplier of materials utilized under this project for their review.

## **ATTACHMENT B**

**RFP-NIH-NIAID-DMID-01-03**

**December 30, 1999**

### **REPORTING REQUIREMENTS AND DELIVERABLES**

#### **REPORTING REQUIREMENTS**

The contractor shall submit to the Contracting Officer (CO) and the Project Officer (PO) technical progress reports covering the work accomplished during each reporting period. These shall be factual and prepared in accordance with the following format:

- A. Semi-annual Technical Progress Reports. The contractor shall submit 4 copies 30 calendar days following the end of each six month period. Each semi-annual report shall consist of:
  1. A cover page containing:
    - a. Contract number and title
    - b. Period of performance being reported
    - c. Contractor's name and address
    - d. Author(s)
    - e. Date of submission
  2. A Table of Contents
  3. A detailed description of the work performed during the report period.
  4. A discussion of the work's significance, problems encountered, and measures taken.

5. Summary tables of results.

6. Plans for the future.

B. Interim Technical Progress Reports. Often, an interim report on an individual antiviral agent will be required by the PO either to facilitate planning or for reporting to a drug sponsor. These reports will be simple summaries of relevant data with little or no narrative. These are to be provided within 14 days of request by the PO.

C. Annual/Final Reports

The contractor shall submit 4 copies of the annual and final reports which document and summarize the results of the entire contract work for the period covered. For the final report, this shall be in sufficient detail to explain comprehensively the results achieved. Annual reports shall be submitted 30 calendar days following the anniversary date of the contract. The final report shall be submitted by the completion date of the contract. An annual report is not required for the period when the final report is due.

In addition to the sections described in A. 1. above, each report shall contain:

1. SECTION I -- An introduction covering the purpose and scope of the contract effort.
2. SECTION II -- A description of the overall progress plus a separate description of each task or other logical segment of work on which effort was expended during the report period. Descriptions shall include pertinent data and graphs in sufficient detail to explain any significant results achieved and a scientific evaluation of the data accumulated to date under the contract.
3. SECTION III -- A description of current technical or substantive performance and any problems which may exist along with proposed corrective action. An explanation of any difference between planned progress and actual progress, why the differences have occurred and, if behind planned progress, what corrective

steps are planned.

- C. If the contractor becomes unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore.

D. TECHNICAL REPORT DISTRIBUTION

Copies of the technical reports shall be submitted as follows:

| Type of Report       | No. of Copies | Address                                                                                                  | Due Dates                                                                      |
|----------------------|---------------|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Semi-annual Progress | 3             | Project Officer<br>Virology Branch<br>DMID, NIAID, NIH<br>6700B Rockledge Dr.<br>Bethesda, MD 20892-7630 | Semi-Annually<br><br>(Specific dates will be listed in the contract document.) |
| Semi-annual Progress | 1             | Contracting Officer<br>Room 2230<br>CMB, NIAID, NIH<br>6700B Rockledge Dr.<br>Bethesda, MD 20892-7612    | Same as above                                                                  |
| Annual               | 3             | Same as PO above                                                                                         | Annually<br><br>(Specific dates will be listed in the contract document.)      |

|         |   |                  |                                  |
|---------|---|------------------|----------------------------------|
| Annual  | 1 | Same as CO above | Same as above                    |
| Final   | 3 | Same as PO above | Completion date                  |
| Final   | 1 | Same as CO above | Same as above                    |
| Interim | 3 | Same as PO above | 14 days after<br>requested by PO |

## **ATTACHMENT C**

**RFP-NIH-NIAID-DMID-01-03**

**December 30, 1999**

### **EVALUATION FACTORS FOR AWARD**

#### **1. General**

Selection of an Offeror for contract award will be based on an evaluation of the proposals for two factors. The factors in order of importance are: technical excellence; and, cost and other factors. Although technical factors are of paramount consideration in the award of the contracts, costs will be carefully evaluated and the Government reserves the right to make awards to cover multiple genres. Thus, proposals with similar genres will be grouped, and each genre group will be reviewed and scored separately. Those proposals scoring the highest in each genre group will be given highest priority. In accordance with FAR 15.305, proposals will be subject to a cost realism analysis by the Government.

The evaluation will be based on the demonstrated capabilities of the prospective contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

A single Offeror may submit a proposal which includes one or more viruses and one or more models for a single virus. Each model pertaining to a single virus should be clearly marked in the Technical Proposal so as to facilitate the technical review of that model. The technical proposal should also include sufficient cost information for each genre. (See RFP Attachment F, Forms, Formats, and Attachments, Technical Proposal Cost Information.) Within the proposal, all models pertaining to viruses of the same genre should be grouped together. Each viral genre will be scored separately and a competitive range will be determined for each. It is anticipated that one or two awards will be made for each viral genre, which may or may not include all of the proposed models. Awards will be made on the basis of the technical merit of each model as determined through peer review, the relevance and uniqueness of each model in relation to Program priorities and balance, and the availability of funds. It is possible that an Offeror will be asked to delete one or more models from the proposal during negotiations.

Although technical factors are of paramount consideration in the award of the contract(s), costs will be carefully evaluated and the Government reserves the right to make awards to cover multiple genres. Thus, proposals with similar genres will be grouped, and each genre group will be reviewed and scored separately. Those proposals scoring the highest in each genre group will be given highest priority.

If more than one viral genus is proposed, the business proposal should include a separate cost estimate for each genus as well as a cost estimate which combines all proposed viral genera. In the event that the technical evaluation reveals that Offerors are technically equal, then cost will become the deciding factor. Offerors are advised that award will be made to that Offeror whose proposal provides the best overall value to the Government.

**Models for herpesviruses, orthopoxviruses, respiratory syncytial virus, and influenza viruses are a priority for NIAID, but offerors are also encouraged to proposed models for other important emerging and/or rare viral infections.**

**Animal models for viral hepatitis, retrovirus, and papillomavirus infections will NOT be considered for award since these are subjects of other NIAID initiatives or are already otherwise being supported by other NIAID funding sources.**

## **2. TECHNICAL EVALUATION CRITERIA**

Proposals will be technically evaluated for each proposed viral genus in accordance with the following factors, which are listed and weighted according to their relative importance:

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <u>Weights</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <b>A. SCIENTIFIC CONSIDERATIONS</b>                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>65%</b>     |
| 1. Applicability and suitability of the proposed virus and animal model(s) to evaluate the clinical potential of experimental therapeutic agents for the treatment of human viral diseases. 30%                                                                                                                                                                                                                                                                |                |
| 2. Adequacy and feasibility of the proposed plans and strategies for evaluation of antivirals and the accomplishment of all the objectives of the Work Statement within an appropriate proposed time frame. 35%                                                                                                                                                                                                                                                |                |
| <b>B. PERSONNEL and MANAGEMENT</b>                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>25%</b>     |
| Documented evidence of the qualifications, experience, and availability of <u>all</u> technical personnel in working with infectious diseases and animal model research, in relation to their proposed roles, and of the Principal Investigator in managing complex projects of a similar nature. Documentation regarding corporate experience, adequacy of the management plan and mix of staff, and organizational structure for the conduct of the project. |                |

C. FACILITIES 10%

Documentation regarding the availability and adequacy of the facilities and equipment to carry out the studies proposed.

TOTAL: 100%

**3. HUBZONE PARTICIPATION FACTOR**

Offerors which are qualified HubZone Small Business Concerns will be evaluated in accordance with FAR Clause 52.219-4 (January 1999).

**4. SMALL DISADVANTAGED BUSINESS PARTICIPATION FACTOR (SUBJECTIVE ASSESSMENT)**

Evaluation of the offeror's Small Disadvantaged Business Participation Plan will be based on information obtained from the plan provided by the Offeror (with their business proposal), the realism of the proposal, other relevant information obtained from named SDB concerns, and any information supplied by the Offeror concerning problems encountered in SDB participation.

Evaluation of SDB Participation Plan will be a subjective assessment based on a consideration of all relevant facts and circumstances. The Government is seeking to determine whether the Offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform as the prime Contractor. The assessment of the Offeror's SDB participation plan will be used as a means of evaluating the relative capability and commitment of the Offeror and other competitors. Thus, an Offeror with an exceptional record of participation with SDB concerns may receive a more favorable evaluation than another, whose record is acceptable, even though both may have acceptable technical proposals.

SDB Participation will not be scored, but the Government's conclusions about overall commitment and realism of the Offeror's SDB Participation Plan will be influential in determining the relative merits of the Offeror's proposal and in selecting the Offeror whose proposal is considered most advantageous to the Government.

## ATTACHMENT D

RFP-NIH-NIAID-DMID-01-03

December 30, 1999

### SPECIFIC RFP INSTRUCTIONS AND PROVISIONS

*NOTICE TO OFFERORS: This attachment contains proposal instructions and information that are specifically related to this acquisition. The information provided below is only a portion of the instructions and notices required for the submission of a proposal. References to additional, more general information, and forms regarding proposal preparation are contained in Attachment E, "Applicable RFP References".*

1. **NUMBER AND TYPE OF AWARD(S)** It is anticipated that one (1) award will be made from this solicitation and that the award will be made on/about January 3, 2001, 2000. It is anticipated that the award from this solicitation will be a cost reimbursement completion type contract with a 7 year performance period, and that incremental funding will be used.
2. **ESTIMATE OF EFFORT** It is estimated by the Government that the total labor effort may fall within the ranges listed below. However, this information is furnished for the Offeror's information only and is not to be considered restrictive for proposal purposes.

| Labor Category                 | Annual Effort |
|--------------------------------|---------------|
| PI                             | 50% per year  |
| Professional                   | 200% per year |
| Support                        | 50% per year  |
| Total Estimate Effort Per Year | 300% per year |

### 3. SIC CODE AND SIZE STANDARD

*Note: The following information is to be used by the Offeror in preparing its Representations and Certifications, specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATIONS (FEB 1998), FAR 52.219-1:*

The standard industrial classification (SIC) code for this acquisition is 8731.

(1) The small business size standard is 500 employees. (2) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees. This requirement is NOT Set-Aside for Small

Business. However, the Federal Acquisition Regulation (FAR) requires in every solicitation (except for foreign acquisitions) the inclusion of the Standard Industrial Classification (SIC) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

**4. SERVICE OF PROTEST (AUG 1996) - FAR 52.233-2**

- a. Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

**Hand-Carried Address:**

Nancy Hershey, Contracting Officer

DEA, NIAID, NIH

Room 2230

6700-B Rockledge Drive

Bethesda, MD 20817

**Mailing address (U.S.) Postal Service**

Nancy Hershey, Contracting Officer

DEA, NIAID, NIH

Room 2230

6700-B Rockledge Drive, MSC 7612

Bethesda, MD 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address. The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

**5. GOVERNMENT NOTICE FOR HANDLING PROPOSALS**

AN OFFEROR SHALL PLACE THIS NOTICE ON TOP OF EACH COPY OF ITS TECHNICAL PROPOSAL.

"This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices that the submitter places on this proposal shall also be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR paragraph 315.608-72."

(For information regarding authorized restrictive notices, offerors should refer to the "Confidentiality of Proposals" section, Item F.6, of the STANDARD RFP INSTRUCTIONS AND PROVISIONS, General Instructions.)

6. **PRIVACY ACT SYSTEM OF RECORDS** The Privacy Act will not apply to this contract. No data that can be personally identified with individuals will be collected to accomplish a Department function as part of the requirements of the contract. Records will be filed by organization and not by individuals, and, therefore, the Privacy Act does not apply.
7. **SAFETY AND HEALTH DEVIATION PHS 352.223-70 (AUG 1997)** (a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under the contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration, and other agencies at the Federal, State, and local levels (Federal, State and local regulatory/enforcement agencies.) (b) Further, the Contractor shall take or cause to be taken such additional safety measures as the Contracting Officer, in conjunction with the project or other appropriate officers, determines to be reasonably necessary. If compliance with such additional safety measures results in an increase or decrease in the cost or time required of performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause as set forth in the contract. (c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State, or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State, or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action. (d) If the Contractor fails or refuses to comply promptly with the Federal, State, or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State, or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any such stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.(e) The

Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

## PROPOSAL INTENT RESPONSE SHEET

**RFP No.:** NIH-NIAID-DMID-01-03

**RFP Title:** *"Animal Models of Human Viral Infections for Evaluation of Experimental Therapies"*

Please review the attached Request for Proposals. Furnish the information requested below and return this page by **March 1, 2000**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

☐ DO INTEND TO SUBMIT A PROPOSAL

☐ DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

**Company/Institution Name (print):** \_\_\_\_\_

**Address (print):** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Project Director's Name (print):** \_\_\_\_\_

**Title (print):** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
**Signature/Date:**

**Telephone Number and E-mail Address (print clearly):** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
**Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

*(Continue list on a separate page if necessary)*

RETURN VIA FAX OR E-MAIL TO:

CMB, NIAID, NIH

Room 2230

6700B Rockledge Drive, MSC 7612

Bethesda, MD 20892-7612

Attn: Nancy Hershey

RFP-NIH-NIAID-DMID-01-03

FAX# (301) 480-5253

Email: [nh11x@nih.gov](mailto:nh11x@nih.gov)

## **ATTACHMENT E**

**RFP-NIH-NIAID-DMID-01-03**

**December 30, 1999**

### **APPLICABLE RFP REFERENCES**

*This section identifies the items found in the RFP Web directory entitled RFP REFERENCES that are applicable to this RFP.*

1. The entire file entitled "STANDARD RFP INSTRUCTIONS AND PROVISIONS" is applicable to this RFP, except as otherwise may be modified by the inclusion of an item from the "OPTIONAL RFP INSTRUCTIONS AND PROVISIONS".
2. The following items are applicable from the file entitled "OPTIONAL RFP INSTRUCTIONS AND PROVISIONS":

LATE PROPOSALS, MODIFICATIONS OF PROPOSAL, AND  
WITHDRAWALS OF PROPOSALS, PHS 352.215-10

SMALL, SMALL DISADVANTAGED AND WOMEN OWNED SMALL  
BUSINESS SUBCONTRACTING PLAN (does not apply to small business or to  
work performed in foreign countries)

3. The following items/files are applicable from the subdirectory entitled "FORMS,  
FORMATS, AND ATTACHMENTS":

***Applicable to Technical Proposal***

- Technical Proposal Cover Sheet
- Technical Proposal Cost Information
- Summary of Current and Proposed Activities

***Applicable to Business Proposal***

- Proposal Summary and Data Record, NIH-2043
- Business Proposal Cost Information
- Disclosure of Lobbying Activities, OMB Form SF-LLL
- Excel cost spreadsheet (Template provided)

***To Become Contract Attachments***

- Invoice/Financing Requests Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, May 1997
- Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16), Apr. 1984
- Form NIH 2706 (Financial Report) and Instructions for Completing Form NIH 2706  
Note: Financial reports are not always required. This will be discussed during negotiations.

***Other-to be submitted as directed by Contracting Officer***

- Certificate of Current Cost or Pricing Data, NIH-1397
- Small, Small Disadvantaged, HUBZone and Women-Owned Small Business Model Subcontracting Plan Outline

4. The "Representations and Certifications" are applicable. 5. The "Sample Contract Format-General" is applicable.
5. The "Sample Contract Format-General" is applicable.

## **ATTACHMENT F**

**RFP-NIH-NIAID-DMID-01-03**

**December 30, 1999**

### **HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL**

1. **ABOUT NIAID'S CONTRACT REVIEW ON-LINE (CRON) system** *The National Institute of Allergy and Infectious Diseases is using RFP NIH-NIAID-DMID-00-18 to test the Contract Review On-Line (CRON) system developed by the NIAID. Proposals in response to this Request for Proposal (RFP) will be submitted electronically over the Internet. Adequate security will be provided by using a dedicated server with access restricted through passwords. Following the initial phase of electronic submission by the offerors, proposals will be forwarded to the selected technical reviewers where they will be read and evaluated electronically. The technical review is designed so that a face-to-face meeting is not required. Instead technical reviewers will access proposals through the Internet. Final Revised Proposals (FRPs) will also be submitted and reviewed electronically. This electronic acquisition approach will save the government and, hence, the taxpayer the costs of travel and per diem for the reviewers, and of shipping proposals to the reviewers. Offerors will be spared the cost of copying and shipping proposals, which can be a significant expense. This approach should also reduce the staff time needed to process an action through to award. We anticipate that the savings in staff time will be much greater than the savings in postage and paper costs.*

### **2. ELECTRONIC SUBMISSION INSTRUCTIONS**

*GENERAL --- To submit a proposal electronically under this RFP, Offerors will need to prepare the proposal on a word processor or spreadsheet program (for the cost portions) and convert them to Adobe Acrobat Portable Document Format (PDF). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES. Further, to expedite the file transferring process, the two files must be named using the following DOS naming convention:*

— *Technical Proposal: c:\rfp\_\_\_\_\techprop.pdf*

— *Business Proposal: c:\rfp\_\_\_\_\busiprop.pdf*

*Approximately TWO weeks prior to the due date of proposals, all offerors will be provided with specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contracting Officer identified in this RFP and complete and submit the attached Proposal Intent Form by March 1, 1999.*

*NOTE: There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined below. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 3.0.*

*ADDITIONAL SUGGESTIONS --- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system will not incorporate a capability to read these files. Graphics which are embedded into documents should be kept as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly. Suggestions include:*

- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.*
- Simplify the color palette used in creating figures.*
- Be aware of how large these graphics files become. Large files are discouraged.*
- Limit scanned images as much as possible.*

*PAGE LIMITS -- The narrative portion of the Technical Proposal, (under 4. Technical plan, items a through d) is limited to fifty (50) pages. Pages in excess of this will be removed from the proposal and will not be read or evaluated. Offerors are encouraged to limit the overall size of the Technical Proposal, inclusive of appendices, attachments, etc. Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs. Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around. Technical Proposal and Business Proposal preparation instructions along with proposal table of contents are detailed below.*

## **1. TECHNICAL PROPOSAL INSTRUCTIONS**

*GENERAL --- The entire technical proposal, except as noted below in the "Technical Proposal Table of Contents", is to be submitted electronically. The STANDARD RFP INSTRUCTIONS AND PROVISIONS provide more detail on the TECHNICAL PROPOSAL requirements.*

## **TECHNICAL PROPOSAL TABLE OF CONTENTS/FORMAT**

*(NOTE: Instructions to offerors are indicated in parentheses or as footnotes.)*

1. TECHNICAL PROPOSAL COVER SHEET ..... Page 1
2. TECHNICAL PROPOSAL TABLE OF CONTENTS ..... Page 2
3. SUMMARY OF OBJECTIVES AND METHODS (Abstract)\*... Page 3
4. TECHNICAL PLAN (Refer to Technical Proposal Instructions located in the Standard RFP Instructions and Provisions.)  
STATEMENT OF WORK a.Objectives ..... Page 4  
b. Approach .....  
c. Methods .....  
d. Schedule .....  
PERSONNEL (List by name, title, department and organization, and detail each person's qualifications and role in the Project.) Provide narrative for:  
e. Principal Investigator/Project Director  
f. Other Investigators  
g. Additional Personnel, (e.g., technical support, subcontractors, consultants) (*Note: For key personnel, include 2 page biosketch/resume and the form entitled "Summary of Current and Proposed Activities."*) -- Page \_\_\_\_
5. FACILITIES/RESOURCES AND DIRECT COSTS (List/describe all equipment, facilities and other resources available for this project; attach "Technical Proposal Cost Information" form, and marked laboratory/clinical space floor plan in Item 6.)-- Page \_\_\_\_
6. OTHER CONSIDERATIONS (Provide brief narrative of any unique arrangements, safety procedures in place, animal welfare issues, human subject and minority and gender issues, etc.)-- Page \_\_\_\_
7. HUMAN SUBJECTS, PARTICIPATION OF CHILDREN AND MINORITY AND GENDER ISSUES NOT OTHERWISE ADDRESSED (IF APPLICABLE) -- Page \_\_\_\_
8. "Technical Proposal Cost Information" summary spreadsheet -- Page \_\_\_\_
9. LITERATURE CITED -- Page \_\_\_\_

10. APPENDICES\*\* (Protocols, policy manuals, etc. for above Technical Plan; list each Appendix; Appendices must be clear and legible, and easily located.)

*\* State the proposal's broad, long-term objectives and specific aims. Describe concisely the research design and methods for achieving these goals. DO NOT EXCEED ONE PAGE in providing the abstract. Identify the RFP number, institution, and Principal Investigator on the abstract. \*\* HARDCOPY SUBMISSION OF APPENDICES: The following items are excluded from our electronic submission requirement and will not be subject to page limitations. Offerors may provide appendices electronically or may instead submit ten (10) paper copies of the information.*

#### **4. BUSINESS PROPOSAL INSTRUCTIONS**

- a. **GENERAL --- THE ENTIRE BUSINESS PROPOSAL IS TO BE SUBMITTED ELECTRONICALLY.** *There are no page limits with the business proposal. The **STANDARD RFP INSTRUCTIONS AND PROVISIONS** provide more detail on the BUSINESS PROPOSAL requirements. Following proposal submission and review, additional information will be requested by the Contracting Officer from all offerors that comprise the competitive range. The format of your BUSINESS PROPOSAL is detailed in the "Business Proposal Table of Contents", below. With the Business Proposal, please submit Form NIH-2043, "Proposal Summary and Data Record." Note that in addition to telephone and fax numbers, the INTERNET addresses of both the Principal Investigator and the responsible business representative are to be included on the form.*
- b. **If more than one viral genus is proposed, the business proposal should include a separate cost estimate for each genus as well as a cost estimate which combines all proposed viral genera.**
- c. **ESCALATION.** *Due to the National Institute of Allergy and Infectious Diseases' current budget restrictions, it is recommended that any proposed annual increase in costs for inflation be limited to no more than 3% of total costs per year. Final inflation increases will be subject to the negotiation process taking into consideration the most current consumer price index (cpi).*
- c. **BUSINESS PROPOSAL TABLE OF CONTENTS**

*Please use the following format to organize and present your Business Proposal:*  
**SECTIONS/FORMAT**

1. Proposal Summary and Data Record, NIH-2043
2. Business Proposal Cost Information and cost spreadsheets which include an itemized cost element breakdown, for each year of the contract. Cost elements on these spreadsheets include (as applicable): Direct Labor, Fringe Benefits,

*Materials, Subcontracts, Travel, Equipment, ODC, Raw Materials, Purchased Parts, Indirect Costs, Fee.*

***[Note: We have included a template cost spreadsheet in Microsoft Excel. Offerors are requested to complete this spreadsheet and include it with their business proposal. This spreadsheet can replace the cost sheets that you ordinarily provide. It is our hope that this spreadsheet will provide you with a useful tool, allow us to more easily understand your cost proposal, and eliminate our need to recreate your spreadsheets. This spreadsheet template is a new approach, and we would appreciate any feedback you could give us about it.]***

**3. Business Plan - the business plan has the following components:**

*A narrative of the BASIS of costs proposed; do not provide documentation with initial proposal*

*Qualification of the Offeror - This includes: General Experience, Organizational Experience Related to the RFP, Performance History, Pertinent Contracts and Grants*

*Property, Equipment, Facilities to be dedicated to this work*

*Royalties, Financial Capacity, Subcontractors*

**1. Representations and Certifications**

**2. Other Forms/Information:**

*Disclosure of Lobbying Activities, OMB Form SF-LLL*

**5. PACKAGING AND DELIVERY OF THE PROPOSAL**

*[Note to Offeror: Listed below are delivery instructions for the submission of the PAPER copies of your proposal. Instructions for your electronic submission are described above in Electronic Submission Instructions.] Shipment and marking shall be as indicated below:*

**A. EXTERNAL PACKAGE MARKING:**

*In addition to the address cited below, mark each package as follows:*

*"RFP NO. NIH-NIAID-DMID-01-03"*

*TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"*

**B. NUMBER OF COPIES:**

*The number of copies required of each part of your proposal are as specified below.*

*Technical Proposal: One (1) unbound signed original and one unbound copy, with 10 copies of items excluded from electronic submission requirement that you choose to provide in paper format (SOPs, PERTINENT MANUALS, NONSCANNABLE FIGURES OR DATA, AND LETTERS OF COLLABORATION/INTENT.) Business Proposal: One (1) unbound signed original and one unbound copy.*

**C. PAPER COPIES TO:**

*If hand delivered or delivery service:*

*Nancy Hershey, Contracting Officer*

*Contract Management Branch, NIAID, NIH*

*Room 2230*

*6700-B Rockledge Drive Bethesda, Maryland 20817*

*If using U.S. Postal Service:*

*Nancy Hershey, Contracting Officer*

*Contract Management Branch, NIAID, NIH*

*Room 2230*

*6700-B Rockledge Drive, MSC 7612*

*Bethesda, Maryland 20892-7612*

***NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address. NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with PHSAR 352.215-10, Late Proposals, Modifications of Proposals and Withdrawals of Proposals (NOV 1986).***

